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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,002	10/17/2001	Christoph Andreas Roth	8932-266	3810

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EXAMINER

ROBERT, EDUARDO C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,002

Applicant(s)

ROTH ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 22-24 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 26, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's amendment filed on March 23, 2004 amends non-elected claims 1-16, which were directed to Invention I, so that they depend, directly or indirectly, from independent claim 22, i.e. Invention III. Thus, the restriction requirement between Inventions I and III (mailed on September 23, 2004) is not applicable and it is withdrawn.

In view of the above noted withdrawal of the restriction requirement, applicant(s) are advised that if any claim(s) directed to the Invention I be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 22-24, 26, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Bramlet et al. (U.S. Patent 6,648,889).

Bramlet et al. disclose an implant system comprising a first implant, e.g. 1 (an intramedullary nail), defining a first longitudinal axis, a channel, and a bore 33 in communication with the channel (see Figure 20 below).

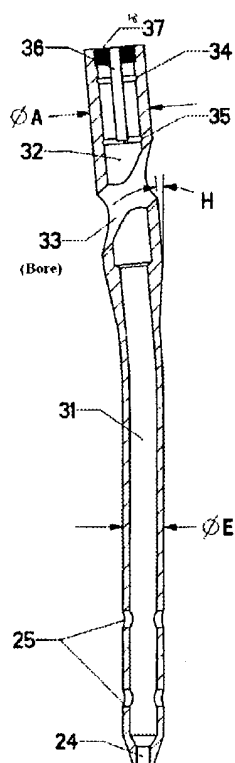
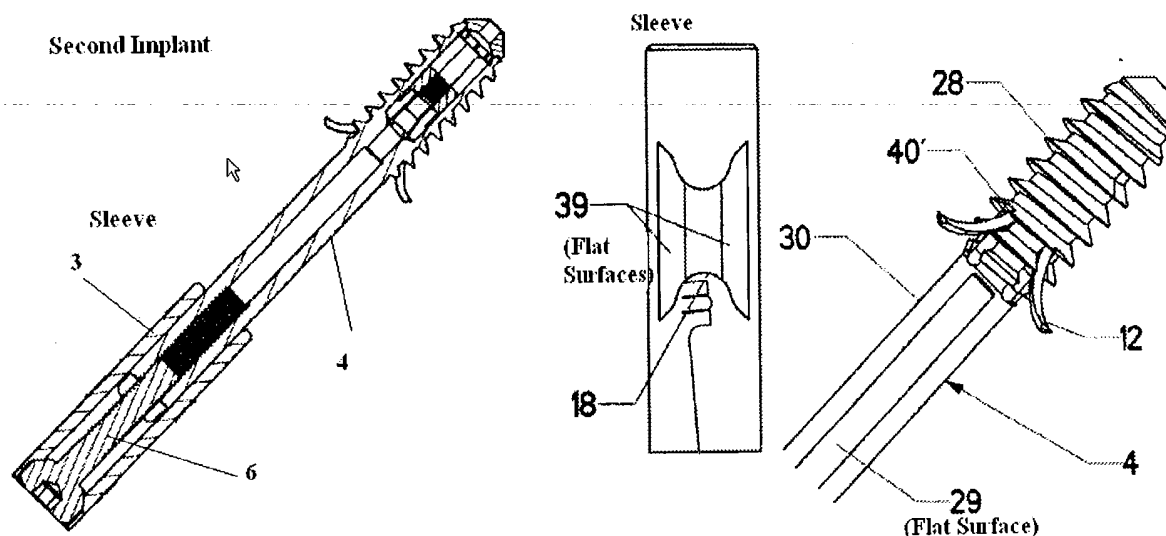


FIG. 20

The bore 33 is disposed at a predetermined angle with respect to the first longitudinal axis. The system also comprises a second implant comprising a screw 6, a sleeve 3 and a screw 4 (see Figure below). The second implant also includes engagement flat surfaces 29 and 39 and stops 18 (see Figure below).

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The second implant defines a second longitudinal axis and it is slidable, i.e. capable of slide, along the second longitudinal axis within the bore 33, it is noted that the second implant could slide within the bore 33 when not in engagement with body member 2, (see Figure 2). The system further comprises a body member 2 receivable in the channel and including at least one flat prong (see for example Figure 8). The prong and second implant are configured and dimensioned to **limit** sliding of the second implant (see for example Figures 4 and 5), i.e. the second implant when engaged by body member 2 would have a limit sliding. The system also has a driver member, e.g. 8 (see Figure 6) rotatably coupled to the body member. The driver member is threadable engage within the channel. The body member and drive member are received in the channel. A cannulation is defined through the first implant, body member and drive member (see Figures 2, 8-10, 16). The at least one prong defines a first engagement surface and the second implant defines a second engagement surface (see Figure 5). The second engagement surface has a first end and a second end longitudinally spaced from the first end, and includes stops formed adjacent at least one of the ends (see Figure 14). The second implant

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includes a plurality of helically twisted threads which can be considered "blades" since they engage the cancellous bone and they are a thin part of a section.

Response to Arguments

Applicant's arguments filed on March 23, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the sleeve 3 does not restrain the lag screw 4 in axial translation to any extent, it is noted that the second implant, as stated in the rejection, is considered to be the combination of screw 6, sleeve 3 and screw 4 (as show above) and the applicant agrees that the sleeve by itself does not limit the axial translation of the second implant, it is the interaction between the body member 2 and second implant part, i.e. sleeve 3, which limit or restrain the sliding movement of the implant, i.e. second implant. It is noted that the second implant is limited to just an extension or retraction of the screw 4.

In response to applicant's argument suggesting that the prong and implant engagement surface of the Bramlet et al. Patent do not interact with each other, it is noted that the prong and implant engagement surface interact with each other so that rotational movement is prevented (see col. 10, lines 27-33).

In response to applicant's argument that the sleeve can not considered the second implant as it is not configure to slide, it is noted that as rejected the sleeve is not considered the second implant. The sleeve is considered part of the second implant, as well as the screws 6 and 4. With regard that the sleeve does not slide, it is noted that examiner points to applicants own words in the remarks, page 8, paragraph six:

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According to the specification of the Bramlet '889 patent, the "slotted sleeve [3] slidably passes through the transverse clearance bore of intramedullary nail and *freely telescopes over the lag screw assembly.*" (Col. 4, ll. 5-7; emphasis added.) Thus, the sleeve

Thus, it is clear that the sleeve slide within the bore.

Allowable Subject Matter

Claims 1-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

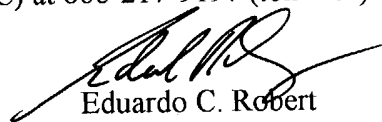
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.